

REMARKS

Applicants intend this response to be a complete response to the Examiner's **21 May 2003 Non-Final Office Action**. Applicants have numbered the paragraphs in their response to correspond to the paragraph numbering in the Office Action for the convenience of the Examiner. Please note that related paragraphs are combined in paragraph number ranges, *e.g.*, 2-3.

General Remarks

The present invention is not obvious over any of the cited reference taken alone or any combination. In fact, the inventor can document prior invention of his device over Takashina et al. However, because Takashina et al clearly teaches away from the present invention (generating pressure pulses without mechanical vibrations - a requirement of this invention), Applicant utilizes Takashina et al to demonstrate how non-obvious the present invention is based on the prior art cited in this Office Action.

Claim Rejections - 35 USC § 103

3. **Claims 1 and 2** stand rejected under 35 U.S.C. 103(a) as being unpatentable over Eggert et al (US 6, 193,519) in view of Lampotang et al (US 5,769,641). Applicant traverses this rejection and requests reconsideration in light of the claim amendments, if any, and the remarks set forth below.

The Examiner contends as follows:

4. Regarding claim 1, Eggert et al discloses a simulation apparatus comprising a plurality of electronic signals corresponding to a heart beat (Col 4, lines 46-62), a tactile pulse signal to detect a pulse signal discernable by touch (Col 6, lines 26-40), and an audio simulator for generating a heart beat signal (Col 4, lines 46-62). Eggert et al does not specifically disclose the generation of a pulse signal or a correlated heart sound. However, Lampotang et al teaches a simulation system which generates a pulse signal and a synchronized heart sound. Therefore; it would have been obvious to one of ordinary skill in the art at the time of invention to provide a system comprising a plurality of electronic signals corresponding to a heart beat, a tactile pulse signal to simulate a pulse signal discernable by touch, and an audio simulator for generating a correlated heart beat signal. Combining the system disclosed

by Eggert et al with the teaching of Lampotang et al produces a system that closely corresponds to a real patient.

Applicant acknowledges that Eggert et al. generates sounds, particularly heart beat sounds. However, Applicant disagrees the Eggert et al. includes pulse simulators that generate a tactile output designed to be detected by touch. The tactile switches of Eggert et al are designed to ensure proper attachment of the cuffs 18d and 18e to the manikin.

FIGS. 5a-5d illustrate details of the BP cuff 18d and the pulse oximeter finger cuff 18e. The cuffs 18d, 18e are configured together wherein a cable 86 is provided that connects to the BP/OSAT/HEARTRATE port 48 and bifurcates into the respective cuffs. Electrical leads 86a and 86b connected to the respective cuffs 18d and 18e are depicted at one end of the cable 86 in FIG. 5b for connection to the EKG port 48 (FIG. 3). As shown in FIGS. 5c-5d with respect to the finger cuff 18e, **a tactile switch 88 connected to a line 90 of the cable 86 is mounted in the finger cuff and is activated to complete a circuit when the cuff is secured properly with velcro (male) 91a and velcro (female) 91b to the finger of the manikin 28. Similar switch circuitry, though not shown, is contained in the BP cuff 18d.**

Eggert et al at Col. 6, ll. 26-40 (emphasis added). The tactile switches are not devices that allow a user to place his/her finger on the switch and discern a pulse; instead they are devices used to complete a circuit.

Moreover, Eggert et al. uses virtual instruments. The entire purpose of the present invention is to require a student to use actual instruments – his/her finger and a real stethoscope. The problem solved by this invention is the fact that medical students often graduate without basic skills in utilizing their fingers and a stethoscope as a first line diagnostic for detecting heart and/or circulatory abnormalities. Using virtual instruments regardless of their sophistication does not overcome this problem.

When using the present invention, the student is confronted with recordings of real heart sounds and correlated pulse sensations that require the students to hone their skills in perceiving normal heart and circulatory rhythms from abnormal heart and circulatory rhythms. In its simplest form, the present invention comprising a playback device, a tactile output device and an audio output device. A student places her/his finger on the tactile output device and the listening end of a stethoscope on the audio output device, and the

playback device sends correlated pulse signals and heart sound signals to the output devices. Nothing in Eggert et al discloses, teaches or suggests combining two different sensory output devices (speaker and a tactile output device) to educate a student on the proper use of a hands on technique for front line diagnostics using correlated output signals.

Lampotang et al does nothing to eliminate these basic deficiencies of Eggert et al. While Lampotang et al does relate to a simulator for simulating human responses during medical procedures. Although the manikin is capable of generating lung and heart sounds, only the lung sounds are synchronized with anything and that is "normal and abnormal breath sounds are synchronized with the bellows movement." Lampotang et al at Col. 12, ll. 38-40. As far as Applicant's attorney can determine, the Lampotang et al manikin does not include any tactile output devices. Applicant's attorney search the patent extensively for every conceivable verbal description of such as device and found none. Moreover, Lampotang et al does not disclose, teach or suggest ensuring that the heart sounds and pulses going to the EKG are correlated. Clearly, the pulse network is synchronize so that pulse propagation profiles can be simulated in the device. However, this pulse simulation system does not produce a signal detectable by touch. Therefore, a combined Eggert et al and Lampotang et al device would have no mechanism of outputting an output detectable by human touch that can be correlated to heart sounds. Thus, the combined device fails to even suggest correlating touch and sound, the two key ingredients in a device to train medical students in the proper use of a stethoscope and touch as a front line diagnostic.

Because neither Eggert et al, Lampotang et al nor their combination disclose, teach or suggest a device including a tactile sensory output device, especially one correlated to heart sounds, the present invention is not obvious for Eggert et al in view of Lampotang et al. Applicant, therefore, respectfully requests withdrawal of this section 103(a) rejection.

The Examiner contends as follows:

5. Regarding claim 2, Eggert et al discloses a simulation apparatus comprising a plurality of electronic signals corresponding to a heartbeat (Col 4, lines 26-45) distributed in an appropriate fashion, left side or right side, required by the training regimen (Col 6, lines 40-52), and an audio simulator for generating a heart beat signal (Col 4, lines 26-45) that may be heard

through a stethoscope. Eggert et al does not specifically disclose the generation of a pulse signal or a correlated heart sound. However, Lampotang et al teaches a simulation system which generates a pulse signal and a synchronized heart sound. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a system comprising a plurality of electronic signals corresponding to a heart beat, a tactile pulse signal to simulate a pulse signal discernable by touch, and an audio simulator for generating a correlated heartbeat signal in an appropriate position, whether that is the left or right side. Combining the system disclosed by Eggert et al with the teaching of Lampotang et al produces a system that provides more flexibility for training staff.

Applicant incorporates the previous arguments herein, and further notes that claim 2 is not obvious in view of Eggert et al and Lampotang et al because claim 2 differs from claim 1 only in the addition of a second tactile output device, a device not disclosed, taught or suggested in Eggert et al, Lampotang et al or their combination.

Because neither Eggert et al, Lampotang et al nor their combination disclose, teach or suggest a device including a tactile sensory output device, especially one correlated to heart sounds, the present invention is not obvious for Eggert et al in view of Lampotang et al. Applicant, therefore, respectfully requests withdrawal of this section 103(a) rejection.

6. **Claims 8-24** stands rejected under 35 U.S.C. 103(a) as being unpatentable over Eggert et al in view of Lampotang et al in further view of Takashina et al (US 6,461,165). Applicant traverses this rejection and requests reconsideration in light of the claim amendments, if any, and the remarks set forth above and below.

The Examiner contends as follows:

7. Regarding claim 9, Eggert et al discloses that the audio simulator housed within a housing (Col 4, lines 37-44 and Fig. 2). Eggert et al does not specifically disclose a tactile simulator housed within a housing. However, Takashina et al teaches that a tactile simulator may be housed within a housing that simulates a manikin (Col 2, lines 22-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator with audio and tactile simulators housed within a housing. Combining the system disclosed by Eggert et al with the teaching of Takashina et al provides a system that is more self-contained and easily used.

Applicant incorporates the previous arguments herein, and further notes that Takashina et al does not remedy the deficiencies of Eggert et al or Eggert et al in view of Lampotang et al. Although Takashina et al simulates both heart sounds and pulses, Takashina et al uses air to generate the pulses so that the pulses are generated "without generating any mechanical vibration." Takashina et al at Col 2, ll. 24-25. Adding Takashina et al to Eggert et al or Eggert et al combined with Lampotang et al gives rise to an air activated pulse/heart sound simulator. In fact, Takashina et al, by requiring pulse generation without mechanical vibration, teaches squarely away from the present invention that requires mechanical vibrations to generate the pulses. Moreover, the present invention is distinguished from these references in that the pulses are mechanically generated and the correlated heart sounds are generated by a speaker.

Because the combination of these three references does not disclose, teach or suggest a combination of mechanical pulse generators coupled with audio output devices for correlated heart sounds and in fact the addition of Takashina et al teaches squarely away from using mechanical or electromechanical devices to generate the pulse, the combination does not render claim 9 obvious. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

8. Regarding claims 11 and 17, Eggert et al discloses that the audio simulator housing is contained by a simulator that simulates an upper part of a human body including simulated chest and arm portions (Col 2, lines 27-54 and Figure 2). Eggert et al does not specifically disclose a tactile simulator housing that is contained by a simulator that simulates an upper part of a human body including simulated chest and arm portions. However, Takashina et al teaches that a tactile simulator may be housed within a housing that simulates a manikin including simulated chest and arm portions. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator with audio and tactile simulators housed within a simulator that simulates an upper part of the human body including simulated chest and arm portions. Combining the system disclosed by Eggert et al with the teaching of Takashina et al. provides a system that better represents the human body.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

9. Regarding claims 8, 10, 13, 16, and 19, Eggert et al discloses a simulator designed to represent a patient, such as a manikin, with a plurality of sensors and electronic signals to represent a plurality of physical diagnostic signals such as anyone of a plurality of body noises including heart and lung sounds (Col 4, lines 46-62). Eggert et al does not specifically disclose that a tactile pulse simulator comprises any one of a tactile switch, collapsible tube apparatus or piezoelectric transducer (claims 8 and 16) or that the tactile simulator comprises a resilient cover over a tactile switch (claims 10, 13 and 19). However, Takashina et al teaches that a simulated pulse may be derived from a collapsible tube apparatus built within a simulator comprising a manikin (Col 2, lines 22-35). Takashina also teaches that the tube apparatus is made of a soft rubber or synthetic resin so as to reproduce feeling in a finger that is similar to the human body diagnosis (Col 2, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator comprising a manikin with a tactile pulse simulator consisting of a collapsible tube apparatus with a resilient cover over a tactile switch. Combining the patient simulator disclosed by Eggert et al with the teaching of Takashina et al produces a training simulator that has the appearance of a human system and provides a realistic pulse tactile signal.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

10. Regarding claim 12, Eggert et al discloses a simulator, apparatus wherein pulse simulation signals are detected in a simulated arm in a first housing and audio is detected from the chest, a second housing (Col 6, lines 27-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in the wrist of the simulator (claim 12). However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and the audio simulator located in the chest portion. Combining the simulator disclosed by Eggert et al with the teaching of

Takashina produces a simulator that most closely matches the audio and pulsation locations on a human body.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

11. Regarding claim 14, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm in a first housing and audio is detected from the chest (Col 6, lines 26-52). Eggert et al does not specifically disclose that the tactile sensor and the audio sensor are located in two separate housings. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) and that the audio sensor may be located in a second housing (Col 2, lines 52-56). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and the audio simulator located in the chest portion. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator that provides a more accurate teaching methodology for students.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

12. Regarding claim 15, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm and audio is detected from the chest (Col 6, lines 26.-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in the wrist of the simulator or that the tactile simulator comprises a resilient cover over a tactile switch. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) and that a tube apparatus is made of a soft rubber or synthetic resin so as to reproduce feeling in a finger that is similar to the human body diagnosis (Col 2, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and that the tactile simulator comprises a resilient cover over a tactile switch. Combining the simulator disclosed by Eggert et al with the teaching of

Takashina produces a simulator in which diagnosis points are located in a fashion to emulate the human body for better training of medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

13. Regarding claims 18, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm (Col 6, lines 26-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in either wrist of the simulator. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) including pulsation points in both left and right wrists. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in both a right and left simulated wrist in the body of the simulator. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator with the ability for multiple use by training professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

14. Regarding claims 20 and 22, Eggert et al discloses a simulator apparatus for generating pulse and heart beat simulations comprising a simulated upper body portion with a chest and left and right arm portions, a playback device for generating electronic signals corresponding to pulse and heartbeat signals, a tactile pulse simulator and a heart beat signal within the chest housing of the simulator with the heart beat detectable by a stethoscope (Col 2 and Col 3). Eggert et al does not specifically disclose a left and right pulse signal, or that the pulse signal is a pressure pulse signal. However, Takashina teaches that a pressure pulse signal may be generated through flexible tubing (Col 2, lines 23-53) and that pulsation signals are sent to detection locations on both the right and left wrist of a manikin simulator (Fig. 2). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a training simulator apparatus for generating pulse and heart beat simulations comprising a simulated upper body portion, a playback device for generating electronic signals corresponding to pulse and

heartbeat signals, a tactile pulse simulator and a heart beat signal within the chest housing of the simulator with the heart beat detectable by a stethoscope with detectable pulsation signals in a left and right wrist location. Combining the apparatus disclosed in Eggert et al. with the teaching of Takashina produces a training simulator that closely resembles the subjects for which the simulator is designed providing a realistic training environment for medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

15. Regarding claim 21, Eggert et al discloses a simulator designed to represent a patient, such as a manikin, with a plurality of sensors and electronic signals to represent a plurality of physical diagnostic signals such as any one of pulse, heart beat, or lung sounds (Col 4, lines 25- 62). Eggert et al does not specifically disclose that the tactile, pulse simulator comprises any one of a tactile switch, collapsible tube apparatus or piezoelectric transducer.. However, Takashina et al teaches that a simulated pulse may be derived from a collapsible tube apparatus as a tactile pulse simulator built within a simulator comprising a manikin (Col 2, lines 22-35). Therefore it , would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator comprising a manikin with a tactile pulse simulator. Combining the patient simulator disclosed by Eggert et al with the teaching of Takashina et al produces a training simulator that has the appearance of a human system and provides a realistic pulse tactile signal.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

16. Regarding claim 23, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm (Col. 6, lines 26-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in either wrist of the simulator. However , Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) including pulsation points in both left and right wrists. Therefore, if would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator

wherein the pulse simulator is located in both a right and left simulated wrist in the body of the simulator. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator with the ability for multiple use by raining professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

The Examiner contends as follows:

17. Regarding claim 24, Eggert et al discloses a simulator apparatus wherein pulse simulation signals are detected in a simulated arm and audio is detected from the chest (Col 6, lines 26-52). Eggert et al does not specifically disclose that the tactile sensor for the pulse is located in the wrist of the simulator or that the tactile simulator comprises a resilient cover over a tactile switch. However, Takashina teaches that pulsation sensors are located at all major correspondence points with the human body the simulator is designed to represent (Fig. 2) and that a tube apparatus is made of a soft rubber or synthetic resin so as to reproduce feeling in a finger that is similar to the human body diagnosis (Col 2, lines 36-39). Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to provide a simulator wherein the pulse simulator is located in a simulated wrist and that the tactile simulator comprises a resilient cover over a tactile switch. Combining the simulator disclosed by Eggert et al with the teaching of Takashina produces a simulator in which diagnosis points are located in a fashion to emulate the human body for better training of medical professionals.

Applicant incorporates the previous arguments herein, and again, the combination fails to render obvious this invention. Applicant, therefore, respectfully requests withdrawal of this rejection.

New Claims

New claims 25 to 27 are directed to an apparatus similar to that of claim 2, but where each simulator is housed in a separate housing. Because neither Eggert et al, Lampotang et al, nor their combination renders claim 1 or 2 obvious as stated above, Eggert et al, Lampotang et al, or their combination does not render these newly added claims obvious.

If it would be of assistance in resolving any issues in this application, the Examiner is kindly invited to contact applicant's attorney Robert W. Strozier at 713.977.7000

Date: **October 6, 2003**

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'Robert W. Strozier', is written over a horizontal line.

Robert W. Strozier

Reg. No. 34,024